VERIFICATION STATEMENT

I hereby state that the content of the paper copy of the corrected sequence listing and the enclosed computer-readable copy of the corrected sequence listing are the same.

REMARKS

Applicant hereby submits a corrected computer-readable copy of the sequence listing, a copy of the sequence listing printed on paper, and the above sequence listing Verification Statement.

The disk has been checked using the USPTO Checker Version 4.1 program, and no errors were found.

By way of this Office Action (Paper No. 1), the Examiner has required restriction to one of the following inventions under 35 U.S.C. §121 and §372: Groups I-XVII. Specifically, claims 1, 2 and 20 are linking for Groups I-V which are broken down as follows:

Group I includes claims 3 and 11, drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping an individual in a Fas ligand promoter region directed to a polymorph which is active in binding NF-IL6 transcription factor;

Group II includes claims 4, 5, 10 and 12 which differ from the claims of Group I in binding TCF/LEF-1;

Group III includes claims 5 and 7 and relates to haplotyping an individual in a Fas ligand promoter region at position -756;

Group IV includes claims 5 and 8 and is drawn to haplotyping an individual in a Fas ligand promoter region at position -478;

Group V includes claims 5 and 9 and is drawn to haplotyping an individual in a Fas ligand promoter region at position -205;

Group VI includes claim 6 drawn to genotyping a Fas ligand promoter to identify susceptibility to a disease;

Claim 13 is linking for Groups VII-X which are restricted as follows:

Group VII includes claim 14 drawn to a Fas ligand promoter polymorph which is -844 C/T;

Group VIII includes claim 15 drawn to a Fas ligand promoter polymorph which is -756 A/G;

Group IX includes claim 16 drawn to a Fas ligand promoter polymorph which is -478 C/T;

Group X includes claim 17 drawn to a Fas ligand promoter polymorph which is -205 C/6;

Group XI includes claims 18, 19 and 21 drawn to primers and kits for Fas ligand promoters;

Group XII includes claims 24-26 and 31 drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping a Fas promoter for a polymorph at -690;

Group XIII includes 24-26 and 31 drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping a Fas promoter for a polymorph at -95;

Group XIV includes claims 27 and 28 drawn to a Fas promoter single nucleotide polymorph which is -690 T/C or greater than -660 or less than -680;

Group XV includes claims 27 and 29 drawn to a Fas promoter single nucleotide polymorph which is -95 G/A or greater than -660 or less than -680;

Group XVI includes claim 30 and is drawn to a kit for Fas promoter; and

Group XVII includes claim 32 drawn to genotyping Fas promoter polymorphisms for determining susceptibility to a disease.

Responsive to the requirement for restriction, Applicant elects to prosecute the invention of Group I drawn to a method for determining autoimmune disease or cancer susceptibility by haplotyping an individual in a Fas ligand promoter region directed to a polymorph which is active in binding NF-IL6 transcription factor. Applicant makes the election of Group I **with traverse**. Applicant respectfully requests modification of the restriction requirement to allow prosecution of Groups I-XI designated by the Examiner in the present application for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions . . . in one Application may . . . be restricted to one of the inventions." Inventions are "independent" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related . . . but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification;
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it

on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, 8th Ed., 2001) (emphasis added).

Applicant respectfully submits that those claims relating to Fas ligand promoter polymorphs, claims 1-21, have not been identified as having separate classification, separate status in the art or different field of search. To the extent that a single nucleotide polymorph, such as those identified at positions -844, -756, -478 and -205, represent different nucleotide sequences, then these sequences should nonetheless be examined in concert as a result of the partial waiver requirements of 37 CFR 1.41 per 1192 OG 68 (November 19, 1996) (cited at MPEP 803.04). As the total number of single nucleotide polymorphs with respect to Fas ligand promoter is four and the total number of single nucleotide polymorph combinations only adds an additional nine sequence variations, it is submitted that these sequences should likewise be prosecuted together with the subject matter of Group I.

The MPEP states: "Nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together." (MPEP 803.04). With respect to the pending claims of Groups I-XI, the nucleotide sequence regardless of polymorphs nonetheless continues to operate as a Fas ligand promoter and therefore remains within the intended meaning of the above-referenced examination procedure of MPEP 803.04.

The claims of restriction Groups I-XI have not been shown, and are unlikely to be categorized separately according to the Manual of Patent Classification and therefore would not require an additional search. Additionally, the restriction requirement detailed in Paper No. 1 fails to advance an argument that the Fas ligand promoter has a different status in the art depending on single nucleotide polymorphisms therein. As such, it is respectfully submitted that none of the elements detailed above from MPEP 808.02 are present. Thus,

Applicant submits that the search and examination of Groups I-XI can be made without serious burden, and therefore the Examiner must examine these claims in the application on the merits as required by the MPEP.

It is stated in Paper No. 1 that Groups I-V are patentably distinct from each other "because they are drawn to methods that detect different polymorphisms. Each polymorphism results in a nucleic acid sequence that is both structurally and functionally different." Likewise, Groups VII-X are considered patentably distinct from one another because "they are drawn to different polymorphisms which result in nucleic acid sequences that are both structurally and functionally different." (Paper No. 1, section 2, pages 3 and 4). Group VI is considered distinct from Groups I-V as including different methodology steps. However, this distinction ignores the commonality of the Fas ligand promoter as being the subject sequence. The statement that the polymorphisms of Groups I-V and VII-X being structurally and functionally different is respectfully submitted to be misplaced. Regardless of the single nucleotide polymorphisms, the resulting nucleotide sequences still function as Fas ligand promoters. Additionally, there is no indication of a different structural sequence resulting from the single nucleotide polymorphisms detailed herein.

The Examiner's assertion to the contrary notwithstanding, Applicant respectfully submits the conjoint examination and inclusion of claims 1-21 of the present application would not present an undue burden on the Examiner, and accordingly, modification to include the claims in Groups II-XI is believed to be in order.

Summary

By way of this amendment, a replacement computer-readable sequence listing is provided that does not differ from the sequence listings as filed. The pending claims are

amended to correct typographical defects. Applicant elects with traverse Group I and respectfully requests that the restriction requirement be modified to include Groups II-XI.

Respectfully submitted,

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Enclosures

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DATE OF DEPOSIT October 31, 2003

I hereby certify that this paper or fee (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service "Express Mail Post Office To Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Janice R. Kuehn